

## § 73.4

## 42 CFR Ch. I (10–1–12 Edition)

Fever virus (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis* must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin.

(ii) For all other HHS select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after seizure of the agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for three years.

(4) The Federal law enforcement agency reports the final disposition of the select agent or toxin by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for three years.

[70 FR 13316, Mar. 18, 2005, as amended at 70 FR 61049, Oct. 20, 2005; 73 FR 61365, Oct. 16, 2008; 73 FR 64554, Oct. 30, 2008]

### § 73.4 Overlap select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety, to animal health, or to animal products.

(b) Overlap select agents and toxins:

*Bacillus anthracis*

*Brucella abortus*

*Brucella melitensis*

*Brucella suis*

*Burkholderia mallei* (formerly *Pseudomonas mallei*)

*Burkholderia pseudomallei* (formerly

*Pseudomonas pseudomallei*)

Hendra virus

Nipah virus

Rift Valley fever virus

Venezuelan Equine Encephalitis virus

(c) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:

(1) Nucleic acids that can produce infectious forms of any of the overlap select agent viruses listed in paragraph (b) of this section.

(2) Recombinant nucleic acids that encode for the functional form(s) of any overlap toxins listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*, or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) Overlap select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Overlap select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any overlap select agent or toxin that is in its naturally occurring environment provided that the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Non-viable overlap select agents or nonfunctional overlap toxins.

(e) An attenuated strain of an overlap select agent or toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain does not pose a severe threat to public health and safety, to animal health, or to animal products.

(1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be published periodically in the notice section of the FEDERAL REGISTER and will be listed on the CDC Web site at <http://www.cdc.gov/>.

(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting overlap select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the HHS Secretary for reconsideration of a decision denying an exclusion application. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any overlap select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the select agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized select agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process,

(2) The Federal law enforcement agency safeguards and secures the seized select agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin, and

(3) The Federal law enforcement agency reports the seizure of the overlap select agent or toxin to CDC or APHIS.

(i) The seizure of *Bacillus anthracis*, *Brucella melitensis*, Hendra virus, Nipah virus, Rift Valley fever virus, or Venezuelan equine encephalitis virus must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after seizure of the select agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for three years.

(4) The Federal law enforcement agency reports the final disposition of the overlap select agent or toxin by the submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for three years.

[70 FR 13316, Mar. 18, 2005, as amended at 73 FR 61366, Oct. 16, 2008]

#### § 73.5 Exemptions for HHS select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a HHS select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of

this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary, within seven calendar days after identification, the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law.

(i) The identification of any of the following HHS select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: Botulinum neurotoxins, Ebola viruses, *Francisella tularensis*, Lassa fever virus, Marburg virus, South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis*. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

(ii) For all other HHS select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after identification.

(iii) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(iv) A copy of APHIS/CDC Form 4 must be maintained for three years.

(b) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a HHS select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,